

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS FO Box 1430 Alexandria, Virginia 22313-1450 www.tepto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/556,123	11/09/2005	Steffen Panzner	N015-7001US0	4731	
21127 7590 (2000) RISSMAN HENDICKS & OLIVERIO, LLP 100 Cambridge Street Suite 2101 BOSTON, MA 02114			EXAM	EXAMINER	
			NGUYEN, QUANG		
			ART UNIT	PAPER NUMBER	
2001011,1111	. 02111		1633		
			NOTIFICATION DATE	DELIVERY MODE	
			09/09/2009	ELECTRONIC	

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mbien-aime@rhoiplaw.com cjoseph@rhoiplaw.com info@rhoiplaw.com

### Advisory Action Before the Filing of an Appeal Brief

Application No.	Applicant(s)	
10/556,123	PANZNER ET AL.	
Examiner	Art Unit	
QUANG NGUYEN, Ph.D.	1633	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 31 August 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

- 1. X The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
  - a) The period for reply expires 4 months from the mailing date of the final rejection.
  - b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
    - Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

The Notice of Appeal was filed on . A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

# **AMENDMENTS**

- 3. X The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
  - (a) ☑ They raise new issues that would require further consideration and/or search (see NOTE below);
    (b) ☐ They raise the issue of new matter (see NOTE below);

  - (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for
    - appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims.
    - NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).
- The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
- Applicant's reply has overcome the following rejection(s):
- 6. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
- 7. X For purposes of appeal, the proposed amendment(s): a) X will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
  - The status of the claim(s) is (or will be) as follows:
  - Claim(s) allowed: Claim(s) objected to:
  - Claim(s) rejected: 1.3-6.19-22.35 and 37-43.
  - Claim(s) withdrawn from consideration: 2.23-34 and 36.

#### AFFIDAVIT OR OTHER EVIDENCE

- 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
- 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
- 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

- 11. X The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
- Note the attached Information Disclosure Statement(s), (PTO/SB/08) Paper No(s).
- 13. Other:

/QUANG NGUYEN/ Primary Examiner, Art Unit 1633 Continuation of 3. NOTE: The scope of the proposed claims is not the same as that of finally rejected claims, particularly with the new limitations "gas-free" liposomes, "liposomes consisting of" and "combining with at least one cationic or pH sensitive cationic lipid", which would require further considerations and/or search.

Continuation of 11. does NOT place the application in condition for allowance because: it is noted that most of Applicant's arguments are directed to proposed claims with the new limitations "gas-free" liposomes and "liposomes consisting of"; but these arguments are moot since the proposed claims were not entered for the reasons discussed above. Applicant's other arguments relevant to the rejections of record are not found persuasive for the reasons discussed below.

1. With respect to the Gregordiadis reference, Applicants argue basically that the reference does not teach the use of "claimed protein or peptide active" substances or delayed release.

Please note that rejected claims 38, 40 and 42 simply recite "at least one active substance", and DNA encoding an antigen is an active substance. The liposome system of Gregoriadis has the same components as the liposome recited in the rejected claims, and therefore the liposome of Gregoridadis has the same properties, including a delayed release of an active substance, particularly Gregoridadis taught that a nucleic acid is complexed with liposomes and preferably the nucleic acid is at least partially entrapped (col. 4, lines 39.42).

With respect to the Unger reference, Applicants argue basically that the reference does not teach a "delayed release" system as there his used by Applicants since rupture of the liposomes as taught by Unger can only result in burst release without the possibility of a continuing release.

Please note that the term "depot system for the delayed release of active substances" is not defined by the present application. Paragraph 15 does not contain the definition of the term. Additionally, it is noted that a depot system which add "burst release" is only a preferred embodiment of the present invention. Furthermore, the rejected claims do not require any sustained release or long-term release of any active substance. Accordingly, the teachings of Unger meet the limitation of the finally rejected claims as broadly written.